NOV 2 1 2003

K033565

Sec. 3
510(k) Summary
LMT nomag IC 1,5

LMT

Applicant	LMT Lammers Medical Technology GmbH Bessemerstr. 7 23562 Luebeck Germany
Contact Person:	Thomas Michael Bohnen Tel: +49-451-58098-14 Fax. +49-451-58098-15 Email: bohnen@lammersmedical.com
Common Device Name	Neonatal Transport Incubator
Device Panel:	General Hospital
Product Code Regulation No.	FPL 880.5410
Class	2
Propietary Name	LMT nomag IC 1,5
Performance Standard:	IEC 60601-2-20 IEC 60601-1 ISO 10993
Legally marketed device	Hill-Rom Air-Shields TI 500 K#001019

LMT

Intended Use of the LMT Nomag IC 1,5

LMT nomag IC 1,5 is an infant incubator system for temporary use during MR-imaging in clinical environments and in combination with a suitable trolley for intra hospital transport.

LMT nomag IC 1,5 provides a controlled environment of warmth and humidity for premature babies and sick infants up to a body weight of 4,5 kg (10 lbs) and a maximum body length of 55 cm (21.7 inches).

LMT nomag IC 1,5 is suitable for MR scanner of field strengths up to 1.5T.

Function of the Device

The LMT Nomag IC 1,5 is an incubator for preterm and term-born infants who are scheduled for Magnetic Resonance (MR) Imaging and are dependant on warming therapy. It provides a microclimate of air temperature and humidity suiting the infants needs. The incubator has a trolley for intra clinical transport providing power.
The incubator runs in air control mode and has closed loop control for both air temperature and humidity. Humidification works hygienically via vaporizing of distilled water.

Design and Specifications
The basic incubator performance of the LMT nomag IC 1,5 is defined by the IEC particular standard and thus similar to commercially available incubators.
The technologies used for providing incubator functions are similar to legally marketed devices.

Testing under MR influence
The MR compatibility has been proven in patient and bench testing.

The images were evaluated regarding Signal to Noise Ratio (SNR) and artefacts like geometric distortion, ghosting and uniformity. The decrease in imaging quality (i.e. loss of SNR) was 0 to 2% for most sequences. This value is considered acceptable compared to the benefits of continuous warming therapy throughout scanning.

The compatibility with MR scanners of different manufacturers (Siemens, GE, Philips all 1,5T) have been tested according to an established protocol using phantoms.

SE Statement

The LMT Nomag IC 1,5 incubator is substantially equivalent to the legally marketed device with respect to the incubator functions. It is compliant with international harmonized standards for incubators by the IEC.
The behaviour of the incubator under the special environmental conditions during MR imaging have been tested and have shown no adverse effects in neither direction. The incubator performance was not influenced in any way by the scanner and the imaging has not shown significant artefacts caused by the incubator. Other functions of the scanner were also not influenced by the incubator. The testing did not rise new risks or questions associated with the use of a MR compatible incubator.

The LMT Nomag IC 1,5 1,5T works as safe and effective as the legally marketed device.

T. M. Bohnen

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Thomas Michael Bohnen
Manager R&D
LMT Lammers Medical Technology GmbH, Germany

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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LMT Lammers Medical Technology GMBH
C/O Ms. Susan A. Gill
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive, P.O. Box 13995
Research Triangle Park, North Carolina 27709-3995

Re: K033565
Trade/Device Name: LMT nomag IC 1,5
Regulation Number: 880.5410
Regulation Name: Neonatal Transport Incubator
Regulatory Class: II
Product Code: FPL
Dated: November 6, 2003
Received: November 12, 2003

Dear Ms. Gill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: LMT nomag IC 1,5

Indications for Use:

LMT nomag IC 1,5 is an infant incubator system for temporary use during MR-imaging in clinical environments and in combination with a suitable trolley for intra hospital transport.

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Patricia Cucinotta

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033565

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)